4 510(k) Summary of Safety and Effectiveness

510(k) Summary

510(k) number

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Device: Tempus 2000 Patient Monitor
Tempus Monitoring Station

Classification: 74 DPS 21 CFR; 870.2340

Electrocardiograph
DPS 21 CFR; 870.2340

Non-invasive blood pressure measurement system
DXN; 21 CFR 870.1130

Oximeter
DQA; 21CFR 870.2700

Clinical electronic thermometer
FLL; 21 CFR 880.2910

Analyzer, carbon-dioxide, gaseous-phase
CCK; 21 CFR; 868.4100

4.1 Intended use

The Tempus 2000 Patient Monitor System is intended to be used when a medical situation arises at a location remote from readily available medical expertise. Situations demanding use of the Tempus 2000 Patient Monitor System can occur at remote land locations on private yachts while sailing at considerable distances from land, and during flight on commercial /private jets as well as in other situations.

The Tempus 2000 Patient Monitor is intended to be used by trained non-experts upon people presenting as unwell. It is designed with the most ease of use for the operator so that it can be used quickly, reliably, with minimum training and with little or no support from medical staff. This allows the Tempus 2000 Patient Monitor to be used as either a stand-alone monitor or also connected to the Tempus Monitoring Station. In the latter mode, the Tempus 2000 Patient Monitor connects to a sister device, called the Tempus Monitoring Station, allowing the recorded data to be viewed, stored and manipulated by trained medical staff.

The Tempus Monitoring Station is a normal, commercial grade PC which is dedicated to running the software that enables it to communicate with the Tempus 2000 Patient Monitor. The Tempus Monitoring Station is installed at a Response Centre (typically an emergency room within a hospital) and is operated by experts from the hospital staff. The operator at the Response Centre is able to receive voice calls and data on the patient's condition for assessment and consequently advise on an appropriate course of action. Such action may include advice on treatments to stabilize the condition, or instructions to return to land or divert from the planned journey, if the patient is at sea or in the air.

4.1.1 Indications/Contraindications

4.1.1.1 Indications

The Tempus 2000 Patient Monitor is a patient monitor intended to be used in remote locations where medical staff may not be present.

The device is intended to be applied to the patient by a trained operator who is not a medical expert. The device is not intended to allow the operator to make any clinical decision for treatment or diagnosis. The device permits the operator to take measurements from a patient, store this information for later transmission or transmit medical information to a Response Centre at the time of recording, where trained staff can make clinical assessments based on the information transmitted and advise the operator on the nature of the

medical incident. A trained physician may use the Tempus 2000 Patient Monitor as a standalone diagnostic device.

The Tempus 2000 Patient Monitor is suitable for use on adults or children (over 10 years old and over 20kg in weight).

4.1.1.2 Contraindications

The Tempus 2000 Patient Monitor is not intended to be used on extremely small or extremely large patients; this limit is set by the physical limits of the ECG harness.

The device is not intended to, and does not, sound alarms for physiological parameters. The device does not replace physician's care. The device is not intended for neonatal use. The device is not an apnoea monitor. The device is not intended to be a long term monitor, it is only intended to be used in short, discrete incidents where the immediate health of the patient is in question.

The device is not intended to be used in strong magnetic or electro-magnetic fields which are generated for medical purposes e.g. MRI.

The ECG is not suitable to be used on patients with prosthetic limbs.

4.2 Device description

The Tempus 2000 Patient Monitor is a portable, multi-parameter patient monitor. The unit is housed in a plastic enclosure and comprises:

- a screen
- battery pack
- a removable (attached) wrist mounted keypad which incorporates a digital camera
- the patient monitoring devices
- A foam block (which provides storage locations for the various patient and control devices)

The device can measure the following parameters:

- ECG (Electro Cardio Graph) using a 12-lead harness
- non-invasive blood pressure (three cuff sizes provided)
- temperature (infra-red tympanic)
- respiration rate
- end-tidal exhaled CO_2
- $Sp0_2$ (blood oxygen saturation) for a single patient

The device accumulates the patient physiological data and displays the data in numeric and graphical form to the operator and, remotely, to a Response Centre via two modem connections (for voice and data). All of the data is transmitted in real time with the exception of large files (ECGs and videos). The device can either be used with or without a connection established, in the latter case the information recorded is stored for transmission later.

Operator interface with the device is by 8 control buttons (with an additional button on the thermometer, a battery power level button and an on/off button on the front panel) and by graphical help-screens that are displayed in a logical sequence for ease of use. The helpscreens are displayed for all operations including operating the main medical functions, cleaning and repacking the unit and clearing basic errors that can be expected when using the system e.g. blood pressure hose occlusions.

The device is fitted with a colour, digital video-stills camera for transmitting images of the patient to the Response Centre.

The Tempus 2000 Patient Monitor is designed to connect only to a PC which is configured with the Tempus Monitoring Station software. This software is essentially the same software as that which is installed on the Tempus 2000 Patient Monitor except that the patient data management module is activated. The software contains all the same functions of the Tempus 2000 Patient Monitor (including the ability to select the different functions of the Tempus 2000 Patient Monitor) and in addition has features for the analysis of ECG, the annotation of the digital photographs and the storing of the recorded patient information and results.

In addition, the Tempus Monitoring Station enables the Response Centre operator to:

- Record patient details e.g. name, age, sex etc.
- Record details of the incident e.g. location, time, personnel present etc.
- Record general notes regarding the incident
- View a patient record chart where all the recorded data is displayed in a single form
- View and compare details of previous incidents involving the same patient

4.3 Predicate Devices

We consider the RDT Tempus 2000 to be substantially equivalent to a combination of features offered by predicate systems:

- the Protocol Systems "Propaq Encore" K945071 (including the "Acuity Central Station" K935846 and the Propaq modification K921497),
- the Instromedix LifeSigns™ K964408,

- the Spacelabs Medical Integrated Multiparameter Module 90496, K972502 (including the Spacelabs Medical Ultraview™ Digital Telemetry System K983996).

The device is of a similar size and weight to the predicate monitors. It has the same indications for use (measuring of the same patient parameters, transmitting the information to another location) with the exception that the Tempus 2000 does not have alarms. The intended use differs in that the Tempus 2000 is intended to be used by trained non-medical experts rather than clinical staff (in this intended use it is similar to the Instromedix Lifesigns).

The Tempus 2000 uses similar technology to the predicate monitors and has similar operating specifications. The Tempus 2000 is also tested to the same standards as the predicate monitors.

4.4 Testing

The design of this device utilises currently available (OEM) technology found in many legally marketed devices. In addition, the overall package of features and the intended use of the Tempus 2000 are equivalent to those of other patient monitors that are currently cleared to market. In terms of measurement performance, the Tempus 2000 is effectively identical to the devices that incorporate the same OEM technology.

In terms of application, the Tempus 2000 is similar to the patient monitors that have been identified as predicate devices. The Tempus 2000 differs from these products in its intended use (for use by non-expert users in remote locations). Specifically, it is designed to have the same measurement and data transmission capabilities as the predicate monitors, but be easy to use.

Consequently, the testing that has been applied falls into three categories:

- Testing of measurement facilities – Tempus 2000 has been bench tested to show that the performance of the Tempus 2000 is comparable to the predicate devices.
- Testing of factors that affect such patient monitors e.g. environmental, safety, EMC, performance (program based on relevant standards from FDA guidance documents, those standards identified by the risk analysis as being necessary, those used by predicate devices and those recognised as being applicable to the intended use for the Tempus 2000.
- Testing of aspects specific to the Tempus 2000 e.g. software, ease of use, lithium batteries etc.

In addition, the various FDA reviewers' guides for the individual aspects of the Tempus 2000 were reviewed to ensure that their requirements were included in the verification and validation plans for the product.

The results of the testing demonstrated that the device was in compliance with the guidelines and standards referenced in the various reviewers' guides for the individual product types involved, and that it performed within its specifications and functional requirements.

4.5 Software

The requirements of the FDA document *Guidance for the Content of Premarket Submissions for Software in Pre-Market Submissions* has been applied. In addition, the requirements of EN60601-1-4 have been addressed.

4.6 User trials

Throughout the development of the product, potential user feedback has been sought. Consequently, the Tempus 2000 has been developed with user requirements being added and developed throughout the development process. In addition, the user interface and system controls have been tested by the use of "uninitiated" user trials where lay persons have been required to navigate through the control systems of the Tempus 2000 (without the device being attached to a patient). Lay users were selected because this group would be the most representative of the intended users of the device. The users were required to give specific feedback on the use of the Tempus 2000 facilities.

This testing process has been performed once at the end of the prototype development stage where the controls, software and helpscreen artwork were representative of the intended design. The process was then repeated during the pilot manufacturing stage using the final design of software, artwork and controls (incorporating the findings of the first test). The second test was used as a gauge of how much the control systems had improved and to confirm that the user interface was acceptable for use in the intended application.

4.7 Clinical tests

Clinical tests have not been performed as all of the medical devices are currently cleared to market in applications that are individually substantially equivalent to the intended use of each medical parameter within the Tempus 2000, e.g. to measure non-invasive blood pressure in non-surgical environments. Comparative testing has shown that the performance of the Tempus 2000 is within the same degree of stated accuracy of performance as the predicate devices. Consequently, the use of clinical investigations to

prove the efficacy of the measurement techniques is not required. The functions and features of the Tempus 2000 that are additional to the measurement of medical parameters have been tested and proven by bench and performance testing.

4.8 Bench tests

All of the OEM measuring devices are effectively unchanged by the act of integrating them into the Tempus 2000. With the exception of the thermometer and the capnometer, all of the OEM products had been previously tested to the requirements of the applicable standards detailing the particular requirements for such products. In the case of the capnometer, the lack of existing certification for the OEM technology required that the applicable standard be applied by RDT. For the other products, an analysis of the requirements showed that the minimal changes made would not affect the continued compliance with those standards.

The evidence to support this judgement was the comparison of results from different Tempus 2000 units with examples of the predicate device systems. With the exception of the ECG testing, five different Tempus 2000 devices were used for the tests with the predicate products. In each case, the results obtained from a patient simulator from each Tempus 2000 unit were compared to the results from the predicate device.

In each case the results showed that the integration of the technology into the Tempus 2000 had not affected the performance of the device.

An analysis of the requirements of each of the applicable FDA Guidance documents, and the applicable product standards gave a list of appropriate documents with which to verify safety and effectiveness. In addition, the standards used to determine safety and effectiveness of the predicate monitors were checked, and where appropriate, applied. These included documents covering the following topics:

- Labelling – ensuring that the specific labelling requirements of the particular standards were applied
- Safety – ensuring that any additional safety related requirements were maintained in the Tempus 2000 e.g. creepage and clearance, leakage currents and defibrillator discharge tests were re-tested as a part of the EN60601-1 and other applicable "part 2" tests
- Environmental – ensuring that where requirements for environmental protection were stipulated e.g. water proofing or endurance tests, these areas were covered as a part of the Tempus 2000 system test program

In the case of the ECG, tests were performed to compare the performance and application of the EGC and the electrode apron together. The ECG was

also tested by comparison to the predicate product. The ECG was also examined for effects of stray EMC from the main system that may have contaminated the trace. All tests found that the performance, safety and effectiveness of the ECG and electrode apron were acceptable.

As a result of these tests and the analysis of the specific requirements, the continued compliance of the following units with the relevant standards is accepted:

- ECG with AAMI EC13 and EN60601-2-27
- NIBP monitor with AAMI SP10 and EN60601-2-30
- Pulse oximeter with EN865: 1997

In the case of the capnometer, the comparative tests were performed between the Tempus 2000 and the predicate device. The system was also tested to the accuracy requirements of EN864.

Since there are no defined standards (EN, IEC etc.) for thermometers, comparative testing was necessary to ensure that the results from the integrated thermometer were within specification. The tests showed that this was the case and that incorporating the device into the RDT product makes no effect on the performance of the thermometer.

4.9 Conclusion

On the basis of these results and the above referenced testing, it is our determination that the device is safe, effective and performs as well as, or better than, the legally marketed predicate device(s).

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Respectfully

Chris Hannan
Product Validation Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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MAY 14 2001

Mr. Chris Hannan
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Re: K010436
Trade Name: Tempus 2000 Patient Monitoring System
Regulatory Class: II (two)
Product Code: DXH
Regulation: 870.2920
Dated: February 6, 2001
Received: February 13, 2001

Dear Mr.Hannan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

510(k) Number (if known): K010436

Device Name: Tempus 2000

Indications For Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010436

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)